

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FORM PTO-1449

Sheet 1 of 1

**LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17328	SERIAL NO.: 09/550,371 10/630,604
APPLICANT: AOKI, ET AL.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE: April 14, 2000	GROUP:

UNITED STATES PATENTS

UNITED STATES PATENTS						
*EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	6,113,915	9/5/00	AOKI	424	236

## FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

**EXAMINER**

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**DATE CONSIDERED**

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce, Patent and Trademark Office		PTO form 1449	Atty Docket No.	Serial No.
			17328 (AP)	09/550,371
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant(s) Aoki et al.		10/630,60
(Use several sheets if necessary)				
		Filing Date October 4, 2000		Group

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
CMK	AA 6,063,768	5/26/00	First			
	AB					
	AC					
	AD					
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					
	AK					

## Foreign Patent Documents

						Translation	
	Document	Date	Country	Class	Subclass	Yes	No
	AL						
	AM						
	AN						
	AO						
	AP						

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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	AR	
	AS	

Examiner CMK Date Considered 4/1/05

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SUPPLEMENTAL  
LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17328 (BOT)	SERIAL NO.: 09/550,371 10/639,604
APPLICANT: AOKI, et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE: APRIL 14, 2000	GROUP: 1653

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	6,113,915	9/5/00	AOKI	424		
	AB						
	AC						
	AD						
	AE						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
CMK	BA	WO 97/34624	9/25/97	PCT			
	BB	WO 96/33273	10/24/96	PCT			
CMK	BC	WO 95/30431	11/16/95	PCT			

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

CMK	CA	Guyer, B., <i>Mechanism of botulinum toxin in the relief of chronic pain</i> , Current Review of Pain, 1999, 3:427-431, XP-001031379
	CB	Carruthers, A., et al., <i>Improvement of tension-type headache when treating wrinkles with botulinum toxin A injections</i> , Headache, Oct. 1999:39:662-665, XP-001031356
	CC	Diaz, J., et al., <i>Management of post-thoracotomy pseudoangina and myofascial pain with botulinum toxin</i> , Anesthesiology, V 91, No. 3, Sep 1999, pp. 877-879, XP-001031347
	CD	Silberstein, S., et al., <i>Botulinum toxin type A as a migraine preventive treatment</i> , Headache 2000:40:445-450, XP-002182692
CMK	CE	Gobel, H., et al., <i>Evidence-based medicine: botulinum toxin A in migraine and tension-type headache</i> , Journal of Neurology, 2001 248 Supp 1: I/34-I/38, XP-002182693

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LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17328(AP)	SERIAL NO.: 09/550,371	10/639,604
APPLICANT: Aki et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN	
FILING DATE: 04/14/2000	GROUP: 1646	

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CK	AA 6,063,768	5/16/00	FIRST			
	AB					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n )
	BA					
	BB					

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

CK	CA	Cheng, Guang-Shing; <i>Botox, Dermabrasion Treated Facial Leiomyomas; Skin &amp; Allergy News</i> 2000;31(3):16.
	CB	First, E. et al.; <i>Painful Cervical Dystonia: Response to Treatment with Botulinum Toxin; Mov Disord</i> 1998;13(Suppl2):100.
	CC	Guyer, Barry M.; <i>Mechanism of Botulinum Toxin in the Relief of Chronic Pain; Curr Rev Pain</i> 1999;3(6):427-431.
	CD	Li, Yan, et al.; <i>A Single Mutation in the Recombinant Light Chain of Tetanus Toxin Abolishes Its Proteolytic Activity and Removes the Toxicity Seen after Reconstitution with Native Heavy Chain; Biochemistry</i> 1994, 33, 7014-7020.
CK	CE	Schantz, Edward J., et al.; <i>Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine; Microbiological Reviews</i> Mar. 1992, pp. 80-99, Vol. 56, No. 1.
not in file	CF	Tarsy, Daniel, et al.; <i>Painful Cervical Dystonia: Clinical Features and Response to Treatment With Botulinum Toxin; Mov Disord</i> 1999;14(6):1043-1045.
CK	CG	Zhou, Liqing, et al.; <i>Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain; Biochemistry</i> 1995, 34, 15175-15181.
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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	5,714,468	2/3/98	BINDER			
	AB	5,766,605	6/16/98	SANDERS ET AL.			
CMK	AC	5,989,545	11/23/99	FOSTER ET AL.			

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CMK	BA	94/15629	7/21/94	PCT			
	BB	96/33273	10/24/96	PCT			
	BC	98/07864	2/26/98	PCT			
CMK	BD	99/17806	4/15/99	PCT			

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(Including Author, Title, Date, Pertinent Pages, etc.)

CMK	CA	Barwood, Shane, et al.; <i>Analgesic Effects of Botulinum Toxin A: A Randomized, Placebo-Controlled Clinical Trial</i> ; <i>Developmental Medicine &amp; Child Neurology</i> , 2000; 42:116-121
	CB	Bigalke, H., et al.; <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> ; <i>Brain Research</i> , 360 (1985); 318-324.
	CC	Bigalke, H., et al.; <i>Tetanus Toxin and Botulinum A. Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations from Rat Brain and Spinal Cord</i> ; <i>Naunyn-Schmiedeberg's Arch. Pharmacol</i> (1981); 316:244-251.
	CD	Cheshire, et al.; <i>Botulinum Toxin in the Treatment of Myofascial Pain Syndrome</i> ; <i>Pain</i> , 1994; 59(1):65-9.
CMK	CE	DiStefano, P. S., et al.; <i>Receptor Mediated Retrograde Axonal Transport of Neurotrophic Factors is Increased After Peripheral Nerve Injury</i> ; <i>Progress in Brain Research</i> (1994); Vol. 103; Chapter 4; 35-42.

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OTHER ART (Continued)  
(Including Author, Title, Date, Pertinent Pages, etc.)

CMK	CF	Dixon, W. J.; <i>Efficient Analysis of Experimental Observations</i> ; <u>Ann. Rev. Pharmacol. Toxicol.</u> (1980); 20:441-462.
	CG	Dubuisson, D., et al.; <i>The Formalin Test: A Quantitative Study of the Analgesic Effects of Morphine, Meperidine, and Brain Stem Stimulation in Rats and Cats</i> ; <u>Pain</u> (1977); 4:161-174.
	CH	Duc, C., et al.; <i>Ultrastructural Localization of SNAP-25 Within the Rat Spinal Cord and Peripheral Nervous System</i> ; <u>The Journal of Comparative Neurology</u> (1995); 356:152-163.
	CI	Fauci, A.S., et al. (Editors); <u>Harrison's Principles of Internal Medicine</u> , 14 <sup>th</sup> Edition (1998); McGraw-Hill; 2064-2065.
	CJ	Garner, C.G., et al.; <i>Time Course of Distant Effects of Local Injections of Botulinum Toxin; Movement Disorders</i> ; Vol. 8, No. 1; 1993.
	CK	Habermann, E.; <i>Inhibition by Tetanus and Botulinum A Toxin of the Release of (<sup>3</sup>H)noradrenaline and (<sup>3</sup>H)GABA from Rat Brain Homogenate</i> ; <u>Experientia</u> 44 (1988); 224-226.
	CL	Habermann, E.; <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> ; <u>Naunyn Schmiedeberg's Arch. Pharmacol.</u> ; 281, 47-56 (1974).
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	CN	Hagenah, R., et al.; <i>Effects of Type A Botulinum Toxin on the Cholinergic Transmission at Spinal Renshaw Cells and on the Inhibitory Action at Ia Inhibitory Interneurones</i> ; <u>Naunyn-Schmiedeberg's Arch. Pharmacol.</u> ; 299, 267-272 (1977).
	CO	Halpern, J.L., et al.; <i>Neurospecific Binding, Internalization, and Retrograde Axonal Transport</i> ; Date Unknown; pp. 221-241.
	CP	Johnson, E., et al.; <i>Biomedical Aspects of Botulinum Toxin</i> ; <u>J. Toxicol.-Toxin Reviews</u> ; Feb. 18, 1999; 18(1):1-15.
CMK	CQ	Jung, H. H., et al.; <i>Expression of Neurotransmitter Genes in Rat Spinal Motoneurons After Chemodenervation with Botulinum Toxin</i> ; <u>Neuroscience</u> (1997); Vol. 78, No. 2; 469-479.

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OTHER ART (Continued)  
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CMK	CR	Kim, S. H., et al.; <i>An Experimental Model for Peripheral Neuropathy Produced by Segmental Spinal Nerve Ligation in the Rat</i> ; <i>Pain</i> , 50 (1992); 355-363.
	CS	Li et al.; <i>Biochemistry</i> ; 33:7014-7020 (1994).
	CT	Mochida, S., et al.; <i>Impairment of Syntaxin by Botulinum Neurotoxin C<sub>1</sub> or Antibodies Inhibits Acetylcholine Release but not Ca<sup>2+</sup> Channel Activity</i> ; <i>Neuroscience</i> (1995); Vol. 65; No. 3; 905-915.
	CU	Naumann, et al.; <i>Botulinum Toxin Type A in the Treatment of Focal, Axillary and Palmar Hyperhidrosis and Other Hyperhidrotic Conditions</i> ; <i>European Journal of Neurology</i> , 1999; Vol. 6(suppl4):S3-S10 and S111-S115.
	CV	Nelson, P.G., et al.; <i>Mouse Spinal Cord in Cell Culture. IV. Modulation of Inhibitory Synaptic Function</i> ; <i>Journal of Neurophysiology</i> ; Vol. 40, No. 5; Sept. 1977; 1178-1187.
	CW	Osen-Sand, A., et al.; <i>Inhibition of Axonal Growth by SNAP-25 Antisense Oligonucleotides in vitro and in vivo</i> ; <i>Nature</i> ; 29 July 1993; Vol. 364; 445-448.
	CX	Pearce, L. B., et al.; <i>Pharmacologic Characterization of Botulinum Toxin for Basic Science and Medicine</i> ; <i>Toxicon</i> (1997); Vol. 35, No. 9; 1373-1412.
	CY	Ragona, et al.; <i>Management of Parotid Sialocele with Botulinum Toxin</i> ; <i>Laryngoscope</i> , 109:August 1999; p. 1344-36..
	CZ	Ransom, B.R., et al.; <i>Mouse Spinal Cord in Cell Culture. I. Morphology and Intrinsic Neuronal Electrophysiologic Properties</i> ; <i>Journal of Neurophysiology</i> ; Vol. 40, No. 5; Sept. 1977; 1132-1150.
	DA	Ransom, B.R., et al.; <i>Mouse Spinal Cord in Cell Culture. II. Synaptic Activity and Circuit Behavior</i> ; <i>Journal of Neurophysiology</i> ; Vol. 40, No. 5; Sept. 1977; 1151-1162.
	DB	Ransom, B.R., et al.; <i>Mouse Spinal Cord in Cell Culture. III. Neuronal Chemosensitivity and its Relationship to Synaptic Activity</i> ; <i>Journal of Neurophysiology</i> ; Vol. 40, No. 5; Sept. 1977; 1163-1177.
	DC	Rees, H., et al.; <i>Do Dorsal Root Reflexes Augment Peripheral Inflammation?</i> ; <i>Neuro Report</i> ; Vol. 5, No. 7; 21 March 1994; 821-824.
CMK	DD	Sanchez-Prieto, J., et al.; <i>Botulinum Toxin A Blocks Glutamate Exocytosis from Guinea-Pig Cerebral Cortical Synaptosomes</i> ; <i>Eur. J. Biochem.</i> (1987); 165:675-681.

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OTHER ART (Continued)  
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CMK	DE	Shantz, E.J., et al.; <i>Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine</i> ; <i>Microbiol Rev</i> ; 56:80-99 (1999).
	DF	Simpson, L.; <i>Botulinum Toxin: Potent Poison, Potent Medicine</i> ; <i>Hospital Practice</i> ; April 15, 1999; 34(4):87-91.
	DG	Singh, B.R.; <i>Critical Aspects of Bacterial Protein Toxins</i> ; <i>Natural Toxins II</i> (1996); Plenum Press, New York; pp. 63-84.
	DH	Tonra, J. R., et al.; <i>Axotomy Upregulates the Anterograde Transport and Expression of Brain-Derived Neurotrophic Factor by Sensory Neurons</i> ; <i>The Journal of Neuroscience</i> ; June 1, 1998; 18(11):4374-4383.
	DI	Tsuda, M., et al.; <i>In vivo Pathway of Thermal Hyperalgesia by Intrathecal Administration of <math>\alpha, \beta</math>-methylene ATP in Mouse Spinal Cord: Involvement of the Glutamate-NMDA Receptor System</i> ; <i>Br. J. Pharmacol</i> (1999); 127(2):449-456.
	DJ	Wiegand, H., et al.; <i>The Action of Botulinum A Neurotoxin on the Inhibition by Antidromic Stimulation of the Lumbar Monosynaptic Reflex</i> ; <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> (1977); 298:235-238.
	DK	Wiegand, H., et al.; <i>I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats After Intramuscular Injection</i> ; <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> ; 292, 161-165 (1976).
	DL	Williamson, L. C., et al.; <i>Clostridial Neurotoxins and Substrate Proteolysis in Intact Neurons</i> ; <i>The Journal of Biological Chemistry</i> ; Mar. 29, 1996; Vol. 271:13; 7694-7699.
	DM	Williamson, L. C., et al.; <i>Differential Effects of Tetanus Toxin on Inhibitory and Excitatory Neurotransmitter Release from Mammalian Spinal Cord Cells in Culture</i> ; <i>Journal of Neurochemistry</i> ; 1992; Vol. 59:6; 2148-2157.
	DN	Willis, W. D.; <i>Pain</i> ; <i>The Rat Nervous System</i> ; Second Edition; 1995; Academic Press, Inc.; pages 725-750.
	DO	Woolf, C. J., et al.; <i>Neuropathic Pain: Aetiology, Symptoms, Mechanisms, and Management</i> ; <i>The Lancet</i> ; June 5, 1999; Vol. 353; 1959-1964.
	DP	Yaksh, T. L., et al.; <i>Chronic Catheterization of the Spinal Subarachnoid Space</i> ; <i>Physiology &amp; Behavior</i> (1976); Vol. 17:1031-1036.
CMK	DQ	Zhou et al., <i>Biochemistry</i> ; 34:15175-15181 (1995).

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**Notice of References Cited**

Application/Control No.

09/550,371 10/630,604

Applicant(s)/Patent Under

Reexamination  
AOKI ET AL

Examiner

Chih-Min Kam

Art. Unit

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Page 1 of 1

## U.S. PATENT DOCUMENTS

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<input type="checkbox"/>	O	WO 94/16029-15629	Jul. 1994	US	Borodic et al.	A61K	37/02	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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## NON-PATENT DOCUMENTS

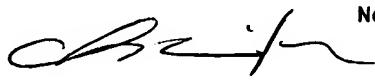
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\*A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)

\*\*APS encompasses any electronic search i.e. text, image, and Commercial Databases.

U.S. Patent and Trademark Office

PTO-892 (Rev. 03-98)


 Notice of References Cited



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